

January 16, 2025

VIA EMAIL and ECF

Hon. Douglas E. Arpert, U.S.M.J. (Ret.)
Three Gateway Center
100 Mulberry Street
15th Floor
Newark, New Jersey 07102

**Re: United States ex rel. Silbersher v. Janssen Biotech Inc., et al.,
Civil Action No. 19-12107 (MEF-SDA)**

Dear Judge Arpert:

Pursuant to your request during our December 17, 2024 status conference, the parties respectfully submit this statement concerning the status of expert disclosures.

Relator's Statement

Relator believes that on August 7, 2024, he provided expert disclosures that complied with the requirements of Fed. R. Civ. P. 26 by disclosing all “facts or data” that the experts considered “in forming” their opinions, *see* Rule 26(a)(2)(B), and satisfying all the other requirements under Rule 26(a)(2). Nevertheless, the parties disagree on the requirements of Rule 26. In an effort to avoid motion practice, Relator has attempted in good faith to accommodate Defendants’ demands by making disclosures and producing documents that he does not believe are required under Rule 26. *See* ECF No. 403. Those accommodations are summarized below.

1. Production of Publicly-Available References

Defendants have requested the *production* of publicly-available references identified in Relator’s expert reports. Although Relator believes that the better reasoned precedent holds that such production is not required, *see* ECF No. 403, at 8-9 (citing cases), Relator has conducted a good faith review of all his expert reports and produced to Defendants such citations, except for certain categories that the parties have agreed need not be produced (*i.e.*, legal citations, regulatory citations and guidance, statutory citations and legislative history, and law review or law journal articles). Relator has also offered to produce any citations or references that may have been inadvertently excluded, or as to which Defendants have difficulty locating. Relator knows of no such documents currently requested by Defendants.

2. Disclosure of Information that Relator’s Experts “Screened” for Relevance

Relator has disclosed all facts and data affirmatively considered by Relator’s experts in forming their opinions that are required to be disclosed under Rule 26. Defendants have argued that documents screened for relevance, but discarded as irrelevant (as opposed to being rejected on substantive grounds), are also “considered” by experts in forming their opinions. If documents were screened for relevance, and deemed relevant, then they were disclosed in the original

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reports. So the parties' dispute is about the disclosure of documents screened for relevance, but deemed irrelevant to this case or otherwise not considered in "forming" the experts' opinions. While Relator disagrees with Defendants' position, to avoid any further delay in the trial schedule and avoid unnecessary motion practice, Relator made a good faith inquiry into documents screened for relevance that were returned from legal database or PubMed searches conducted by two of Relator's experts, Professor S. Sean Tu or Dr. Mark Ratain.

On November 4 and 5, Relator provided Defendants a list of citations that Professor Tu believes he likely would have screened for relevance during his background research, but Professor Tu made clear that he did not "consider" them "in forming his opinion unless he separately cited them elsewhere in his report." Professor Tu is not aware at this time of screening any other documents for relevance for this case outside of general reading for his profession and academic responsibility.

Dr. Ratain has produced medical studies and references he reviewed or screened for relevance only, and which he downloaded to his computer. Dr. Ratain is not aware at this time of screening any other documents for relevance for this case outside of general reading for his practice or other professional and academic responsibilities.

None of Relator's other experts are aware at this time of screening any particular documents for relevance for this case outside of general reading in their respective areas of expertise in the normal course of their academic, professional, or business affairs.

3. Articles and Studies Produced by Dr. Ratain

Dr. Ratain has confirmed that references that "are not cited in the body of [his] report are not as pertinent to the opinions described in [his] opening report as those that are and may have been subject only to a cursory review." Nevertheless, Dr. Ratain has produced, at Defendants' request, medical studies, articles, and other references he reviewed or screened for relevance only, and which he downloaded to his computer. Thus, some documents produced by Dr. Ratain are not directly cited in his report as being facts or data he considered in forming his opinion but are referenced by their Bates numbers.

Relator has asked Defendants if they have particular citations for which they have questions, or for which they would like specific confirmation. Defendants have not identified any further documents.

4. Facts and Data in Trial Preparation Materials

Relator is not obligated to disclose trial preparation materials under Rule 26(b)(3), (4). Relator does not waive or compromise any protections for trial preparation materials contained in Rule 26, or any other source of law, and therefore has not disclosed any trial preparation materials or privileged communications. Nevertheless, Relator has disclosed all facts and data that his experts considered in forming their opinions that are contained in other expert reports or in communications with counsel, including attachments protected as trial preparation materials (without producing such trial preparation or other privileged materials themselves).

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Defendants have now raised, for the first time, their belief that Relator needs to *also* produce trial preparation materials explicitly excluded from discovery under Rule 26(b)(3), (4), such as counsel's privileged and protected communications with the experts—even though Relator's experts disclosed all the underlying “facts or data” that the experts considered, and the assumptions they relied upon, that were contained in such communications. *See, e.g.*, Report of Dr. Hal Singer, at 33 ¶ 60 (detailing assumptions and data considered), filed as ECF 404 Exhibit G; Report of Dr. David Hyman, at 39 ¶ 60, filed as ECF 404, Exhibit E (detailing assumptions relied upon and facts considered). Defendants are simply trying an end-run around the protections of Rule 26(b)(3), (4), and concoct issues to further delay this case. The parties intend to brief this discrete issue with the Court.

5. Defendants' Request for an Extension to Serve Expert Reports

Relator does not believe that any extension is proper or necessary. If anything, what Defendants claimed to be deficiencies in Relator's expert reports were never legitimate reasons to extend their expert report deadlines, because they concerned (at best) minor items that perhaps may relate to deposition topics of the experts, but not whether Defendants should timely serve their *initial and rebuttal* reports. Relator agreed to extend Defendants' expert disclosure date six weeks to January 20 as a matter of professional courtesy. Relator also provided proposed text for this joint letter on December 26, 2024—but the parties have only now, after numerous delays precipitated by Defendants, agreed to this joint letter. Given these delays, Relator acknowledges that a further extension beyond the January 20 date may be *fait accompli*; but Relator believes that should the Court be inclined to extend Defendants' deadline beyond January 20 deadline, any extension not exceed 30 days.

It is simply unfair that Relator timely served his expert reports two months after fact discovery ended on June 6, 2024 (although Defendants *still* have not complied with their fact discovery obligations, including the 30(b)(6) topics that Your Honor ordered in July 2024, ECF 370) without reciprocal disclosure by Defendants. Defendants have still not served even their *initial* reports seven and a half months after fact discovery ended, and now they want three more months.

The imbalance is not merited, particularly since Defendants' primary complaint was that they did not receive production of publicly available documents for which they had hyperlinks. Those do not justify extending Defendants' deadlines or “resetting” their compliance dates—just as Defendants' many (and still outstanding) fact discovery deficiencies did not “reset” the time period for Relator to serve his expert reports after fact discovery. *See, e.g.*, ECF No. 411, at 3. For this reason, Your Honor should reject Defendants' attempt to draw an equivalence between the ten-month extension of fact discovery (which included Relator's review of over 6.5 million pages of documents, plus extensive third-party discovery on numerous generic competitors and government agencies) with their efforts to delay serving expert reports. This is particularly true given Defendants' history of noncompliance with their discovery obligations. *See id.*

Relator therefore adheres to his position that Defendants' motion to extend their expert report deadline should be rejected, and no further extensions should be granted, for the reasons set forth in Relator's letter briefs filed as ECF 406 & 411.

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Relator acknowledges that Defendants agree to withdraw their Rule 26 motion (ECF 391) and motion to strike the expert report of Dr. Hal Singer (ECF 380). Those motions should never have been filed or used as an excuse to delay Defendants' discovery obligations in the first place.

Finally, Relator notes that Defendants' "Timeline" at the end of their section goes well beyond what Your Honor requested for this joint letter, and Defendants are simply trying to supplement their motion for an extension of discovery. This is improper. Relator notes that most of the events they refer to are simply Relator trying to accommodate Defendants' requests for disclosure that go beyond what is required under Rule 26.

In sum, Relator's position is that Defendants have engaged in a strategy to delay these proceedings unnecessarily. None of their complaints about Relator's expert reports justify the delays Defendants have extracted. The best proof of this is the redlines of the expert reports that show exactly how they were amended (ECF 404, Exhibits A through G) (Exhibit G tracks changes from Dr. Hal Singer's August 27, 2024 Supplemental Report adding newly produced CMS data). They speak for themselves, and fairly read, demonstrate that none of the supplements (made to accommodate Defendants to avoid the delays caused by motion practice) justify Defendants' requested extensions, including the seven and a half months (and counting) that Defendants have had to serve their initial reports from the end of fact discovery, and the five and a half months they have had to serve rebuttal reports from the time that Relator served his expert reports.

Defendants did not and do not need months-long delays to adequately prepare their expert reports, and the continued delays are excessive and unfair to Relator, who served his expert reports within two months. This is particularly true considering the vast resources Defendants and their counsel have to litigate this case—and the fact that they have *already* litigated many of the core patent issues in the underlying patent infringement suits and IPRs, where Defendants' counsel even deposed one of Relator's experts (Dr. Mark Ratain) on substantially similar issues. Federal Rule of Civil Procedure 1 instructs that the rules "should be construed, administered, and employed" to secure the "speedy" determination of every action and proceeding. Relator therefore respectfully requests that Your Honor deny Defendants' motion for an additional extension except to provide, *at most*, a 30-day cushion after January 20 based on the late filing of this joint letter.

Defendants' Statement

As discussed during the December 17, 2024 status conference, Defendants have attempted to reach a mutual resolution with Relator regarding (1) the issues raised in Defendants' discovery letter seeking to compel Relator's compliance with Rule 26 (ECF 391); and (2) a new deadline for Defendants' expert reports, which the Court previously stayed.

1. Defendants' Discovery Letter Seeking to Compel Relator's Compliance with Rule 26 for Expert Disclosures (ECF 391): Relator's seven expert reports, served on August 7, 2024 were deficient because they failed to disclose and failed to produce all materials considered by the experts in forming their opinions, as Rule 26 requires. After Relator failed to cure these deficiencies in the meet-and-confer process, Defendants filed a discovery letter on October 22, 2024. Relator subsequently made numerous and extensive amendments and supplements to his experts' reports, catalogued in the Timeline at the end of this statement.

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The need for these amendments and supplements illustrates the deficiencies in Relator's initial reports, and his attempt to minimize them is inaccurate. First, as discussed in Defendants' letter, the problem is not merely that Relator failed to *produce* certain sources, Relator failed even to *disclose* numerous sources considered by the experts. Second, Relator's disclosure failures were not limited only to his exclusion of materials purportedly "screened" by two experts (Tu and Bahr)—an exclusion that has no basis in law. Instead, Relator's initial reports for *all* experts were deficient because they disclosed only the sources relied upon, not "considered," as Rule 26 requires. Further, Relator amended or supplemented his disclosures and reports for *all seven* of his experts—not just Tu and Bahr—and Relator took more than 3 1/2 months to complete these amendments and supplements, well beyond the initial deadline for his expert reports.

On December 26, Relator represented to Defendants that the numerous amendments and supplements he has made to his expert reports now disclose all sources that his experts considered, as Rule 26 requires. Based on that representation, and subject to a new, discrete dispute discussed below, Defendants **withdraw** their discovery letter seeking to compel Relator's compliance with Rule 26 (ECF 391).

Defendants reserve the right to renew their request for Relator's full compliance with Rule 26 if further discovery, including expert depositions, indicate that any of Relator's expert disclosures were incomplete or insufficient.

2. Defendants' Request for an Extension of the Deadline for their Expert Reports (ECF 398): This is Defendants' first extension request; Relator previously has received two extensions totaling 10 months. The bases for Defendants' extension request include (1) the expansive sweep of Realtor's seven expert reports, which stretch far beyond the allegations in Relator's complaint; (2) Defendants' counsel's competing trial commitments; and (3) Relator's extensive delays in making the expert disclosures and productions required by Rule 26.

The Court previously stayed the Defendants' expert report deadline pending the resolution of the issues raised in this letter.¹ As requested in their letter (ECF 398 at 9), Defendants ask the Court to extend the deadline for Defendants' reports by four months from the date Relator demonstrated his compliance with Rule 26—*i.e.*, Defendants ask that the new deadline be set at April 26, 2025 (four months from Relator's December 26, 2024 correspondence with Defendants addressing the Rule 26 issues). *Id.*

This restores the full four-month response period that was agreed to by the parties and approved by the Court. This response period was a key feature of the original scheduling order that the parties negotiated, *see* ECF 213, and its subsequent modification, in which Defendants agreed to Relator's request to a six month extension of fact discovery in exchange for four months to serve their own expert reports, *see* ECF 270. Relator's subsequent non-compliance with Rule 26 has deprived Defendants of the benefit of their earlier bargain.

¹ *See* Nov. 26, 2024 email from Chambers. Relator is therefore mistaken to state that the "deadline" for the expert reports is January 20, 2025. That is merely the position Relator has advocated, not a deadline this Court has adopted.

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Further, the fact that Defendants' expert reports follow Relator's is hardly "unfair," as he protests. Due to the nature of the claims Relator asserts in this litigation, Defendants' expert reports necessarily are responsive to Relator's; Defendants could not appropriately respond to Relator's experts until reviewing their reports. Relator's decisions to proffer expert opinions that sweep well beyond the scope of the Complaint, and to delay for months on his Rule 26 expert disclosures and productions require this extension.

Finally, Defendants advised Relator that they would withdraw their Motion to Strike his damages expert Dr. Singer's Second Amended Expert Report (ECF 380) in exchange for Relator's consent to the April 26, 2025 date. Relator refused, and countered with a March 1, 2025 deadline. Relator's statement above now reverts to his initial position of January 20, 2025. Both of Relator's counter-proposals are insufficient to account for the expansive breadth of Relator's expert reports (which go far beyond the Complaint), or Relator's extensive delays in coming into compliance with Rule 26.²

An extension until April 26, 2025 is appropriate. If the Court agrees to modify the schedule as such, Defendants will withdraw the Motion to Strike (ECF 398).

3. Relator's Improper Withholding of Correspondence Between Counsel and His Experts. Relator recently informed Defendants—for the first time—that he had withheld counsel communications provided to his experts disclosing facts and data the expert considered in forming their opinions. Ex. A at 5–7. Rule 26 expressly requires the disclosures of these communications. *See Fed. R. 26(b)(4)(C)(i)–(iii).* Defendants have requested that Relator identify and produce these documents, but Relator has refused under a baseless assertion of work-product privilege. Defendants therefore plan to file a new, narrow discovery letter seeking to compel the production of these communications—which Relator had not previously identified as withheld.

Defendants do not anticipate seeking a further extension based on Relator's failure to identify these communications, provided that the Court is able to resolve the issues at least 30 days prior to the due date for Defendants' expert reports.

* * *

² Relator's accusation that Defendants attempted to manufacture a de facto extension by delaying the submission of this joint letter is false, and is belied by the Parties' correspondence, which speaks for itself. *See Ex. A.* Defendants contacted Relator the day after the status conference to initiate a resolution, and have worked proactively since to narrow any dispute before the Court. *See id.* Relator's insistence upon using this letter to re-litigate the extension request, which is already fully briefed, and his decision raise a material new issue at the eleventh hour (i.e., his improper withholding of discoverable material, discussed above) materially impacted the timing of this submission, as the correspondence demonstrates.

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Timeline of Relator's Amendments & Supplements to His Expert Disclosures & Productions

August 7, 2024: Relator served expert reports for seven experts on the deadline established by the Scheduling Order.

August 9, 2024: Relator served a First Amended Report for damages expert Dr. Singer, which altered the lower bound of his estimated Aggregate Damages Range by approximately \$430 million.

August 27, 2024: Relator served a Second Amended Report for Dr. Singer which analyzed historical claims data from the Centers for Medicare & Medicaid Services that was not considered in Dr. Singer's original report. As a result of the new analysis, Dr. Singer amended the lower bound of his Aggregate Damages range by \$50 million and the upper bound by \$160 million, substantially increasing the total damages at issue.

September 6, 2024: Relator produced workpapers and materials used by Dr. Singer to calculate damages, which were not disclosed with the original report or the first two amendments.

September 25, 2024: Relator served a First Amended Report for expert Femia, which disclosed sources considered by this expert that were not included in his original report.

October 4, 2024: Relator produced documents and information considered by experts Ratain and Singer, including documents that were not disclosed in Dr. Ratain's original report.

October 24, 2024: Relator produced documents considered by Clark.

November 4, 2024: On this date, Relator:

- Served First Amended Reports for experts Bahr, Clark, and Ratain, which disclosed or identified sources considered by these experts that were not included in their original reports.
- Served a Second Amended Report for expert Femia, identifying additional sources considered by this expert that were not included in the prior versions of his report.
- Served a Third Amended Report for Dr. Singer, identifying sources considered by the expert that were not included in his prior reports.
- Made a first production of sources considered by Bahr, Femia, and Hyman.
- Made a second production of documents considered by experts Clark, Ratain, and Singer.
- Sent an email list disclosing all sources that expert Tu "screened" in preparing his report. Defendants contend that these disclosures are required

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by Rule 26; Relator disagrees, but has made the disclosures to avoid future motions practice.

November 5, 2024: Relator provides Defendants with a revised email list disclosing all sources that Professor Tu “screened” in preparing his report. This amended list removed 35 sources previously identified as “screened” by Professor Tu.

November 7, 2024: Relator served a First Amended Report for Professor Hyman, disclosing sources considered by this expert that were not included in the original report.

November 9, 2024: Relator served a Second Amended Report for Dr. Ratain, adding an exhibit.

November 24, 2024:

- Relator made a first production of sources considered by Tu.
- Relator made a second production of sources considered by Bahr, Femia, and Hyman.
- Relator made a third production of sources considered by Clark.

December 26, 2024: Relator represents to Defendants that the foregoing amendments and supplements he has made to his seven expert reports now disclose all sources that the experts considered, as Rule 26 requires.

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Respectfully yours,

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